

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL)) MDL No. 16-2740
PRODUCTS LIABILITY)
LITIGATION) SECTION: “H” (5)
)
This document relates to:)
Barbara Earnest, 16-17144)

ORDER AND REASONS

Before the Court is a Motion to Exclude Expert Testimony on Specific Causation (Doc. 6162) filed by Defendants Sanofi-Aventis U.S. LLC and Sanofi U.S. Services, Inc. (collectively, “Sanofi” or “Defendants”). The Court heard oral argument on the Motion on July 25, 2019. For the following reasons, the Motion is **DENIED**.

BACKGROUND

Plaintiffs in this multidistrict litigation (“MDL”) are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,¹ that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more. The first bellwether trial of Plaintiff Barbara Earnest (“Plaintiff”) is set to begin September 16, 2019.² In the instant Motion, Defendants seek to exclude testimony on specific causation,

¹ Docetaxel is the generic version of Taxotere.

² To the extent Defendants’ Motion relates to Plaintiff Tanya Francis, the Motion is moot, given the Court’s dismissal of her case. To the extent the Motion relates to Plaintiff Antoinette Durden, the Motion is denied for the same reasons provided herein.

arguing that, under *Daubert*, Plaintiff's experts—specifically, Dr. Curtis Thompson and Dr. Antonella Tosti—do not present reliable evidence on the issue.

LEGAL STANDARD

The admissibility of expert testimony is governed by Federal Rule of Evidence 702, which provides as follows:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.³

The current version of Rule 702 reflects the Supreme Court's decisions in *Daubert v. Merrell Dow Pharms., Inc.*⁴ and *Kumho Tire Co. v. Carmichael*.⁵ The threshold inquiry in determining whether an individual may offer expert testimony under Rule 702 is whether the individual has the requisite qualifications.⁶ After defining the permissible scope of the expert's testimony, a court next assesses whether the opinions are reliable and relevant.⁷ As the

³ FED. R. EVID. 702.

⁴ 509 U.S. 579 (1993).

⁵ 526 U.S. 137 (1999).

⁶ *Wagoner v. Exxon Mobil Corp.*, 813 F. Supp. 2d 771, 799 (E.D. La. 2011); *see also* *Wilson v. Woods*, 163 F.3d 935, 937 (5th Cir. 1999) ("A district court should refuse to allow an expert witness to testify if it finds that the witness is not qualified to testify in a particular field or on a given subject.").

⁷ *See* *United States v. Valencia*, 600 F.3d 389, 424 (5th Cir. 2010). *See also* *Wellogix, Inc. v. Accenture, L.L.P.*, 716 F.3d 867, 881–82 (5th Cir. 2013).

“gatekeeper” of expert testimony, the trial court enjoys broad discretion in determining admissibility.⁸

First, to assess reliability, a court considers whether the reasoning or methodology underlying the expert’s testimony is valid.⁹ The party offering the testimony bears the burden of establishing its reliability by a preponderance of the evidence.¹⁰ Courts should exclude testimony based merely on subjective belief or unsupported speculation.¹¹ Courts must, however, give proper deference to the traditional adversary system and the role of the jury within that system.¹² “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”¹³ After assessing reliability, a court evaluates relevance.¹⁴ In doing so, a court must determine whether the expert’s reasoning or methodology “fits” the facts of the case and will thereby assist the trier of fact in understanding the evidence.¹⁵

Federal Rule of Evidence 703 further provides that an expert may offer opinions based on otherwise inadmissible facts or data but only if (1) they are of the kind reasonably relied upon by experts in the particular field; and (2) the testimony’s probative value substantially outweighs its prejudicial effect.¹⁶

⁸ *Wellogix*, 716 F.3d at 881.

⁹ *See Daubert*, 509 U.S. at 592–93.

¹⁰ *See Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998).

¹¹ *See Daubert*, 509 U.S. at 590.

¹² *See id.* at 596.

¹³ *Id.*

¹⁴ *Burst v. Shell Oil Co.*, 120 F. Supp. 3d 547, 551 (E.D. La. June 9, 2015).

¹⁵ *Id.*

¹⁶ FED. R. EVID. 703.

LAW AND ANALYSIS

To prevail in a pharmaceutical products liability case, a plaintiff must establish both general and specific causation through reliable expert testimony.¹⁷ “General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual’s injury.”¹⁸ The standard method for assessing specific causation is “a differential diagnosis.”¹⁹ “In performing a differential diagnosis, a physician begins by ‘ruling in’ all scientifically plausible causes of the plaintiff’s injury. The physician then ‘rules out’ the least plausible causes of injury until the most likely cause remains.”²⁰

Plaintiff explains that Dr. Tosti is Plaintiff’s primary specific causation expert and that her analysis relied on the work of other experts. Dr. Tosti is a dermatologist who has treated many women for chemotherapy-induced hair loss. In connection with this case, Dr. Tosti recommended that her colleague, Dr. Thompson, conduct a “pathology analysis” for her to consider in forming her opinion on Plaintiff Earnest. This analysis required Dr. Thompson to study “punch biopsies,” or tissue samples, taken from Plaintiff’s scalp. Dr. Thompson explained that as a pathologist, his job was to render “an objective read” on the samples. To create these tissue samples, Plaintiff Earnest, a New Orleans resident, visited a local dermatologist, Dr. Cole Claiborne. Dr. Claiborne took two samples from Earnest’s scalp. Plaintiff’s counsel asked for one from the most affected area of her scalp and one from the least affected area. Heeding

¹⁷ See *Burst v. Shell Oil Co.*, No. 14-109, 2015 WL 3755953, at *3 (E.D. La. June 16, 2015); *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1306 (N.D. Fla. 2018).

¹⁸ *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 351 (5th Cir.2007).

¹⁹ *Wagoner*, 813 F. Supp. 2d at 804.

²⁰ *Id.* (internal citation and quotation omitted); *Porte v. Illinois Cent. R.R. Co.*, No. 17-5657, 2018 WL 4404063, at *3 (E.D. La. Sept. 14, 2018).

this instruction, Dr. Claiborne chose the precise locations for the samples. In her briefing, Plaintiff nicely summarizes the division of labor between Dr. Claiborne, Dr. Thompson, and Dr. Tosti: “[O]btaining the biopsies fell to Dr. Claiborne as the local physician; pathology fell to the expertise of Dr. Thompson; and the overall synthesizing analysis went to Dr. Tosti, who has spent years studying all forms of alopecia.”²¹

I. Defendants’ Arguments Regarding Dr. Claiborne

Defendants first argue that the punch biopsies taken by Dr. Claiborne are unreliable because they were litigation-driven and because Dr. Claiborne did not follow standard practice in taking the biopsies. Defendants note that Dr. Claiborne was not provided with clinical histories or other information needed to make a differential diagnosis. Defendants emphasize testimony from Dr. Claiborne, in which he agreed that outside the litigation context, what was done with Earnest is something he would never do and was not consistent with his clinical practice.

Defendants’ arguments have no merit. Dr. Claiborne was not tasked with conducting a differential diagnosis. Dr. Claiborne’s work was at the direction of Dr. Tosti. As Dr. Claiborne testified, he was a “proceduralist in this instance.”²² Consistent with Dr. Tosti’s instructions, he provided tissue samples for Dr. Thompson to analyze and the differential diagnosis was left to Dr. Tosti. Under Rule 703, an expert can rely on the work of another expert provided that the reliance is reasonable.²³ Defendants have failed to show that

²¹ Doc. 7486 at 4.

²² *Id.*

²³ *See* *Tajonera v. Black Elk Energy Offshore Operations, LLC*, No. 13-366, 2016 WL 3180776, at *10 (E.D. La. June 7, 2016) (“Federal Rule of Evidence 703 allows experts to base their opinions on facts or data that the expert has been made aware of or personally observed, which includes the efforts of other experts, provided that experts in the particular field would

Dr. Tosti unreasonably divided the labor here and jeopardized the reliability of her work in doing so. Further, despite Defendants' argument that Dr. Claiborne's biopsies were litigation-driven, this Court has been provided no opinion that the biopsy process was faulty. Because Defendants have failed to show that his work was unreliable, the Court rejects this argument.

II. Defendants' Arguments Regarding Dr. Thompson

Defendants next argue that Dr. Thompson's opinions are unreliable and irrelevant for three reasons: (1) unreliable biopsies were the foundation of his entire opinion; (2) his methodology failed to account for the specific facts and circumstances of Plaintiff; and (3) his opinion does not answer the relevant question of whether Taxotere, and not something else, caused Plaintiff's alleged permanent alopecia. The Court has already ruled that Dr. Claiborne's work was reliable, leaving only two arguments against Dr. Thompson.

In arguing that Dr. Thompson's methodology was flawed, Defendants re-urge the argument they made with respect to Dr. Claiborne. Defendants take issue with the fact that Dr. Thompson did not consider Plaintiff's clinical history before making a diagnosis. He knew only Plaintiff's age, gender, and the fact that she had chemotherapy treatment. This was, however, consistent with his defined role in Dr. Tosti's division of labor, and Dr. Thompson explained as much in his deposition. He testified that his job was to provide an "objective read" of the tissue samples and that pathologists "focus on getting the information that's important for each diagnosis and not beyond that."²⁴ Notably, he said that a pathologist can be improperly "swayed" in a diagnosis if he has "too much information."²⁵ Further, Dr. Tosti conducted a differential

reasonably rely on those kinds of facts or data in forming an opinion on the subject.") (internal citations omitted).

²⁴ Doc. 7486 at 9–10.

²⁵ *Id.* at 10.

analysis and considered Plaintiff's clinical history and other pertinent information. Thus, the work that Defendants complain was missing was provided—it was provided by Dr. Tosti, not Dr. Thompson. Once again, Defendants have failed to show that Dr. Tosti unreasonably divided the labor here and jeopardized the reliability of her work in doing so.

In arguing that Dr. Thompson's opinions are unhelpful, Defendants point to testimony from Dr. Thompson in which he said that he cannot offer an opinion on which specific chemotherapy drug caused Plaintiff's hair loss. Defendants emphasize again that Dr. Thompson was not provided with Plaintiff's medical history or any information about her background. As the Court has explained, Dr. Thompson conducted his work as part of Dr. Tosti's division of labor. He provided an "objective read" of the tissue samples and then shared his findings with Dr. Tosti, who then conducted a differential diagnosis. It was Dr. Tosti who considered Plaintiff's medical history and other pertinent information. Accordingly, the Court rejects Defendant's argument that Dr. Thompson's opinions are unhelpful and therefore inadmissible. His work served a purpose for Dr. Tosti, and this is permissible under Rule 703.

III. Defendants' Arguments Regarding Dr. Tosti

Defendants raise several attacks against Dr. Tosti. They argue that her opinions must be excluded for three reasons: (1) she relied on Dr. Thompson's unreliable punch biopsies; (2) she failed to reliably rule out other causes; and (3) she relied on literature that is not sufficient to support her ultimate opinion. The Court has already ruled that Dr. Thompson's work was reliable, leaving only two arguments against Dr. Tosti.

Defendants argue that Dr. Tosti conducted a flawed differential diagnosis. Defendants aver that Dr. Tosti did not start by "ruling in" all

scientifically plausible causes of Plaintiff's alopecia and she did not appropriately "rule out" the least plausible causes, including diseases and other medications. Instead, according to Defendants, Dr. Tosti took Dr. Thompson's conclusion that the pathology results were "consistent with permanent alopecia after chemotherapy" and conducted physical examinations to confirm this diagnosis.

Defendants misrepresent Dr. Tosti's report. Dr. Tosti does in fact provide a differential diagnosis. She first explains that alopecia can be classified into one of four categories based on shape and topographic distribution: (1) patchy alopecia; (2) patterned alopecia; (3) marginal alopecia; and (4) diffuse alopecia.²⁶ Making her reasons clear, she concludes that Earnest has diffuse alopecia, and she states that this type of alopecia is seen in four cases: (1) telogen effluvium; (2) diffuse alopecia areata; (3) anagen effluvium due to chemotherapy; and (4) permanent alopecia after chemotherapy.²⁷

Dr. Tosti then explains why she rules out three of these causes. Telogen effluvium results in a positive "pull test," and Dr. Tosti conducted a pull test on Earnest that was negative.²⁸ Further, telogen effluvium is associated with excessive shedding, and Earnest did not present with abnormal shedding.²⁹ Lastly, Earnest has a reduced number of hair follicles "which is not seen in telogen effluvium where the number of follicles is normal."³⁰ In ruling out alopecia areata, she explains that "broken hairs" are a sign of the disease and Earnest's dermoscopy showed no broken hairs.³¹ In addition, Earnest's pull

²⁶ Doc. 7486-19 at 7.

²⁷ *Id.* at 7, 15.

²⁸ *Id.* at 27.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.* at 29.

test was negative, supporting Dr. Tosti's elimination of alopecia areata.³² Lastly, to rule out anagen effluvium, Dr. Tosti against points to Earnest's negative pull test and notes that Earnest had chemotherapy several years ago, allowing Dr. Tosti to eliminate this possible cause.³³

Dr. Tosti further "rules in" and then "rules out" another possible cause, "androgenetic alopecia," even though this type of alopecia does not cause "diffuse alopecia" like Earnest has.³⁴ However, Dr. Tosti explains that endocrine therapy can cause androgenetic alopecia and Earnest has been on Arimidex since 2011.³⁵ In ruling this out, Dr. Tosti provides several reasons, including that the loss of axillary, public, and body hair is not consistent with androgenetic alopecia.³⁶ Elsewhere in her report, Dr. Tosti stated that Earnest had alopecia involving not only her scalp but also her eyebrows, eyelashes, pubic, and axillary hair.³⁷

Accordingly, despite what Defendants argue, Dr. Tosti does in fact "rule in" and "rule out" the plausible causes of Earnest's hair loss.³⁸ Defendants argue that Dr. Tosti should have ruled in other chemotherapy drugs. However, Dr. Tosti reliably opines that Taxotere/docetaxel is the specific chemotherapy agent that caused Earnest's hair loss. She explains that the other two drugs Earnest took, doxorubicin and cyclophosphamide, have only sporadically been reported to cause permanent alopecia. Regarding Taxotere/docetaxel, however, she testified that it is essentially the "one chemotherapy drug that has been reported by many authors to cause chemotherapy-persistent alopecia."³⁹

³² *Id.*

³³ *Id.*

³⁴ *Id.* at 28.

³⁵ *Id.* The Court presumes this is an endocrine therapy.

³⁶ *Id.*

³⁷ *Id.* at 14.

³⁸ Dr. Tosti conducts a similar analysis with respect to Plaintiff Durden. *See id.* at 17–23.

³⁹ Doc. 7486 at 17.

Defendants suggest that a citation to literature has no place in a differential diagnosis, but Defendants cite no cases saying as much. Defendants' concerns seem to be less about Dr. Tosti's methodology and more about her conclusions. Accordingly, the Court finds that Dr. Tosti's differential diagnosis is reliable. To the extent Defendants believe Dr. Tosti drew erroneous conclusions from her work or her research, Defendants can explore this on cross-examination.

CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that Sanofi's Motion to Exclude Expert Testimony on Specific Causation (Doc. 6162) is **DENIED**.

New Orleans, Louisiana this 23rd day of August, 2019.



JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE